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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/087,449	Applicant(s) BLOMQUIST, MICHAEL L.
	Examiner Zoila E. Cabrera	Art Unit 2123

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 November 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/0256/06)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 2, 2007 has been entered.

2. Claims 1-25 are presented for consideration.

Claim Rejections - 35 USC § 102

3. Claims 1-25 are rejected under 35 U.S.C. 102(e) as being anticipated by **Estes et al. (US 2003/0114836)**.

Claims 1-25 are so broad as to read in **Estes**, who discloses a medication delivery system and monitor comprising:

With respect to claims 1-7, **Estes** discloses,

- a method of programming an ambulatory infusion pump from a computer, the ambulatory infusion pump programmed to execute a delivery program, the delivery program being driven by operating parameters (Fig. 1-2), the method comprising: generating a table on a user-interface displayed by the computer, the

table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program (Fig. 3A, element 300; please note that the parameters are entered by the user and such parameters are used to control the pump, see Fig. 1. Estes discloses that status or programming changes are displayed on a display 114, see [0027]); receiving an operating parameter entered into at least one of the cells by a user (Fig. 3A, Table 300 with corresponding operating parameters and cells such as Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3; Page 6, [0054]); and downloading the operating parameters into the pump (Fig. 2, bidirectional communication with Computer 132 and the corresponding Infusion Device or pump. Estes teaches that *the programming can either be entered directly into the infusion device using the input device 108 or transferred from the computer 132 , see Pages 3-4, [0035].*)

- the table includes a plurality of rows, each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump (Fig. 5, Alarm/Event Marker Table);
- at least one cell within each row is configured for a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (Fig. 5, i.e., Susp. On at 12:57 AM);
- the pump has memory and runs a delivery program and downloading the operating parameters includes downloading the operating parameters into the

pump includes downloading the operating parameters into the memory (0035, lines 1-7; Fig. 1, element 106; Fig. 2, element 132, 100);

- the pump is programmed to run a delivery program, the method further comprising running the delivery program, thereby executing the operating parameters (Fig. 6);
- the pump has memory and is programmed to run a delivery program, the method further comprising: downloading all rows of operating parameters to the infusion pump; and storing the operating parameters in the memory (0035, lines 1-7; Fig. 1-2, elements 106, 132; Fig. 3A, element 300);
- 7. The method of claim 6 further comprising: selecting one unique identifying name (Fig. 6, i.e., BOLUS, SUSPEND, or BASAL); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (Fig. 6, i.e., SUSPEND).

As for claim 8, **Estes** discloses

- a method of operating a pump, the pump having a memory and a pump mechanism, the method comprising: receiving from a computer, a plurality of data sets, each data set containing a plurality of operating parameters (Fig. 3A, element 300; Fig. 2, elements 100,132; 0035, lines 1-7; Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from **the event marker table that have been logged by the user**"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format **depending on user's settings**"; [0064],

lines 13-15, i.e., "At least **some of these events can be taken as inputs to the bolus estimator 128** in calculating an insulin dosage"); storing the plurality of data sets in memory (Fig. 1, element 106); selecting one of the plurality of data sets (fig. 6, SUSPEND, BOLUS, BASAL); and running a delivery program wherein the delivery program executes the operating parameters in the selected one of the plurality of data sets, the operating parameters defining a delivery schedule for controlling the pump mechanism (Fig. 6, BOLUS DELIVERY).

With respect to claims 9-11, **Estes** discloses,

- an apparatus for programming an infusion pump, the pump programmed to execute a delivery program, the delivery program programmed to process operating parameters, the operating parameters defining operating of the pump (Fig. 6), the apparatus comprising: a data port; a data entry device (Fig. 2, elements 132, 130); and a processor in data communication with the data port and the data entry device (Fig. 1, element 102), the processor programmed to (a) generate a table on a user interface, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program (Fig. 3A, element 300; please note that the parameters are entered by the user and such parameters are used to control the pump, see Fig. 1. **Estes** discloses that status or programming changes are displayed on a display 114, see [0027]; Fig. 5, Alarm/Event Marker Table); (b) receive data from the data entry device (Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from **the event marker table that have been**

logged by the user"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; [0064], lines 13-15, i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage") and display the data in one or more of the cells (Fig. 1, elements 108, 114; Fig. 5, Alarm/Event Marker Table; Page 6, [0059]-[0061]); and (c) download the operating parameters displayed in the cells to the infusion pump (Fig. 5, i.e., Susp. On 2:00 pm; Page 6, [0060], lines 6-8, i.e., "The event markers can be logged into the pump and stored for later downloading or entered directly into the running software program");

- the processor is further programmed to generate a plurality of rows in the table, each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump (Fig. 5, Alarm/Event Marker Table);
- each row in the table includes at least one cell configured to receive a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (Fig. 5, i.e., Susp. On at 12:57 AM).

As for claims 12-18, **Estes** discloses,

- a method of operating an infusion pump for delivering a therapeutic agent into the body of a user, the infusion pump being programmable and including

memory, the infusion pump being programmed to run a delivery program, the delivery program controlling the infusion pump to deliver the therapeutic agent according to a delivery schedule (Figs. 1-2, 5 and 6), the method comprising: storing a data set in the memory, the data set including a set of operating parameters defining a delivery schedule, at least one of the operating parameters being a user-defined identifying name (Fig. 1, element 106, Fig. 6, BOLUS, SUSPEND, BASAL; Page 6, [0058]); selecting the user-defined identifying name thereby assigning the set of operating parameters identified by the user-defined identifying name to the delivery program (0072, lines 1-9 and lines 15-22); and running the delivery program, the delivery program executing the set of operating parameters thereby controlling the infusion pump to deliver the therapeutic agent according to the delivery schedule defined by the set of operating parameters (0073, lines 1-8; 0072, lines 1-9);

- downloading the data set to the pump from a computer (Fig. 2, elements 132, 100);
- storing, a data set in the memory, includes storing two or more data sets in the memory, each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 6);
- generating a menu, the menu including at least one menu item corresponding to one of the unique identifying names; and wherein selecting the unique identifying name includes selecting the menu item (Fig. 6, MAIN MENU).

- storing a data set in the memory includes storing a plurality of data sets in memory, each data set including a set of operating parameters defining a separate delivery schedule (0074, lines 8-17);
- generating a menu includes generating a menu having at least one menu item corresponding to a unique identifying name from one data set and at least one menu item corresponding to a unique identifying name from another data set (Fig. 6);
- switching execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (0074, lines 1-17).

As for claims 19-25, **Estes** discloses,

- an infusion pump comprising: a pump mechanism (Fig. 2, element 100); memory storing a data set (Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (Fig. 6, Bolus Delivery), at least one of the operating parameters being a uniquely identifying name (Fig. 6, BOLUS, SUSPEND, BASAL); and a processor arranged to control the pump mechanism and in data communication with the memory (Fig. 1, elements 102, 106, 124), the processor being programmed to assign the set of operating parameters to the delivery program upon selection of the uniquely identifying name and to execute the set of operating parameters thereby controlling the pump mechanism to deliver the therapeutic agent according to the delivery schedule (Figs. 5- 6, i.e., BOLUS, SUSPEND, BASAL: 0065, lines 1-20, 0074, lines 8-17);

- a data port, the processor being further arranged to control downloading of the data set and storage of the data set into tile memory (Fig. 2, elements 132, 130, 100);
- the memory stores two or more data sets in the memory, each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 6);
- the processor is further programmed to generate a menu, the menu including at least one menu item corresponding to one of the unique identifying names, wherein selecting the menu item is at least one step in beginning execution of the delivery program (Fig. 6, MAIN MENU);
- the memory stores two or more data sets, each data set including a set of operating parameters defining a separate delivery schedule (0074, lines 8-17);
- the processor is further programmed to generate a menu, the menu including at least one menu item corresponding to a unique identifying name from one data set and at least one unique identifying name from another data set (Fig. 6);
- the processor is further programmed to switch execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (0074, lines 1-17).

Response to Arguments

4. Applicant's arguments filed November 2, 2007 have been fully considered but they are not persuasive.

As for claim 1, Applicant argues that Estes fails to teach all the limitations of claim 1 "generating a table on a user-interface displayed by the computer, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program; receiving an operating parameter entered into at least one of the cells by a user; and downloading the operating parameters into the pump". Examiner disagrees as clearly described with the corresponding citations on paragraph 3 above.

Applicant argues on Page 10,

Estes et al. discloses in Figure 1 an infusion device; Figure 2 illustrates connection of the infusion device to an external computer. Estes et al. discloses use of parameters in Figure 3A in use within the infusion device, rather than the pump. Estes et al. states that Figure 3A refers to a bolus estimator 128, which "is generally activated by the user or health care professional in a setup menu of the external infusion device 100." Estes et al., ¶¶40, 54. The Office Action stresses (1) an illustrated list of pump parameters in Figure 3A, (2) the possibility of bidirectional communication between a computer and the infusion device (Office Action, p. 3), and (3) display of parameters used to control the pump on a display 114 (Office Action, p. 10) to establish that Estes et al. discloses generating a table on a computer. However, (1) the display of pump parameters of Figure 3A occurs on the infusion pump, as previously mentioned; (2) the bidirectional communication between a computer and infusion device does not establish that the computer performs any specific actions; and (3) the display 114 is a display on the pump 100, shown in Figure 1 - not on a computer attached thereto. Entry of operating parameters would therefore also occur based on the display attached to the pump, not on a computer communicatively connected to the pump. Therefore, at least this aspect of claim 1 is not disclosed in Estes et al.

Examiner responds:

Applicant argues that Estes discloses use of parameters in Figure 3A in use within the infusion device, *rather than the pump* and then states that the display of pump parameters of Figure 3A occurs on the infusion pump. It is not clear what applicant is arguing. First of all, Estes discloses that the infusion device can be a medication infusion pump ([0029]). The infusion device or pump includes a display 114 (Fig. 1). The bolus estimator 128 referred in Fig. 3A is activated by the user or a healthcare professional of the external infusion device 100. Therefore the infusion device 100 includes a computer with a corresponding display wherein a bolus estimator is displayed such as the one in Fig. 3A. Estes anticipates generating a table on a computer since the infusion device itself includes a processor and a corresponding display (Fig. 1). Furthermore, Estes clearly discloses that *the programming can either be entered directly into the infusion device using the input device 108 or transferred from the computer 132*, see Pages 3-4, [0035]. Therefore the computer performs specific functions such as programming the infusion device or pump 100.

As for claim 8, Applicant further argues

Regarding claim 8, Applicant notes that the claim requires, among other elements, "a plurality of data sets, each data set containing a plurality of operating parameters". Applicant respectfully asserts that Estes et al. fails to disclose at least this element of the claim. The Office Action indicates that the "SUSPEND, BOLUS, and BASAL" functions are separate data sets which meet this element of the claim. Applicant respectfully disagrees that these functions correspond to the data sets of the claim. First, there is no indication that the functions or parameters run by those functions are received from a computer; rather, as noted by the Office

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Action, the various events corresponding to the SUSPEND, BOLUS, and BASAL functions are "taken as inputs to the bolus estimator 128" - a bolus estimator which Estes et al. indicates is part of the infusion pump, and is not a computer. Even if certain events could be received as inputs to a computer (which Applicant does not concede), these would not constitute data sets, which require a set of inputs received from the computer in the infusion pump. Secondly the SUSPEND, BOLUS, and BASAL functions correspond to delivery programs and not to data sets related to those programs. Estes et al. therefore lacks at least these elements of claim 8.

Examiner responds:

The functions SUSPEND, BOLUS and BASAL are selected and the user inputs the corresponding parameter for each function (see Fig. 6). Each function includes operating parameters such as BOLUS DELIVERLY 0.0 U; SET RESUME BASAL TIME 12:13 PM. Therefore all of these functions correspond to a plurality of data sets, each data set containing a plurality of operating parameters. Applicant argues that there is no indication that the functions or parameters run by those functions are received from a computer but instead are received by the bolus estimator which is not a computer. Examiner wants to point out that the infusion device itself includes a processor with a corresponding display 114 (Fig. 1). Furthermore, Estes clearly discloses that *the programming can either be entered directly into the infusion device using the input device 108 or transferred from the computer 132*, see Pages 3-4, [0035]. Therefore the computer performs specific functions such as programming the infusion device or pump 100.

Regarding claims 12 and 19, applicant argues that Estes does not disclose "a user-defined identifying name". Examiner disagrees because Estes disclose that a daily

report screen as shown in Fig. 5 with a corresponding Patient Name. Therefore, a user of a computer selects and defines a name for a delivery program to be stored in the pump memory.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoila E. Cabrera whose telephone number is 571-272-3738. The examiner can normally be reached on M-F from 8:00 a.m. to 5:30 p.m. EST (every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez, can be reached on 571-272-3753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zoila Cabrera
Primary Examiner
3/16/2008

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/Zoila E. Cabrera/

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